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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------------|------------------|
| 09/597,866 | 06/20/2000 | Michael James Heller | 255/040 | 5697 |
| 34263 | 7590 | 08/14/2003 | | |
| O'MELVENY & MEYERS 114 PACIFICA, SUITE 100 IRVINE, CA 92618 | | | EXAMINER FORMAN, BETTY J | |
| | | | ART UNIT 1634 | PAPER NUMBER |

DATE MAILED: 08/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/597,866 | HELLER ET AL. |
| | Examiner | Art Unit |
| | BJ Forman | 1634 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 28 April 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

4) Claim(s) 49-69 is/are pending in the application.

4a) Of the above claim(s) 49-55 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 56-69 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____ .

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . 6) Other: _____ .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 April 2003 has been entered.

2. This action is in response to papers filed 28 April 2003 in which claims 1-48 were canceled and new claims 49-69 were added. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action dated 28 October 2002 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Election/Restrictions

3. Newly submitted claims 49-55 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: New Claims 49-55 are a previously non-elected invention i.e. a method for enhanced detection of a nucleic acid sample. Claims drawn to the non-elected invention were canceled 5 October 2001 in response to the

Restriction requirement of 13 September 2001. For this reason, Claims 49-55 are withdrawn from prosecution (see MPEM § 819, 921.03 and 37 C.F.R. 1.145).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 49-55 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 56-69 are under prosecution.

Priority

4. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the parent applications filed prior to 09/27/1995 upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 56-69 of this application. The instant claims are drawn to an apparatus comprising a printed circuit board, and a fluidic system comprising an inlet port, outlet port and optical window. Parent applications filed 09/09/1994, 07/07/1994 and 11/01/1993 do not disclose these limitations. Therefore, the parent applications filed prior to 09/27/1995 do not provide support for the instant claims. As such, the effective filing date for the instant claims is 09/27/1995.

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5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 66 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 66 is indefinite for the recitation "PCMCIA" because the recitation is an acronym, the meaning of which may change over time.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 56-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis et al. (U.S. Patent No. 5,846,708, filed 23 April 1992) in view of Wilding et al (U.S. Patent No. 5,726,026, filed 14 November 1994).

Regarding Claim 1, Hollis et al disclose an apparatus for detection of a biological reaction between a sample and an active area of a biochip comprising: a circuit board (Column 14, lines 49-65), a biochip having an active area disposed on the circuit board, a gel permeation layer (Column 21, lines 43-47), and a fluidic system comprising an inlet port and

an outlet port (Column 14, lines 26-65 and Fig. 18-20). Hollis et al do not disclose their apparatus comprises an adhesive that mounts the biochip to the circuit board and they do not teach the fluidic system comprises a window. However, Wilding et al teach a similar apparatus comprising a biochip and a fluidic system wherein the fluidic system further comprises an optical window which facilitates dynamic viewing the contents of the apparatus (Column 10, lines 17-28). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the fluidic system of Hollis et al by incorporating a window into the apparatus as taught by Wilding et al for the expected benefit of facilitating dynamic viewing the contents of the apparatus as taught by Wilding et al (Column 10, lines 17-28). It would have been further obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the apparatus of Hollis et al by incorporating the adhesive mounting taught by Wilding et al for the expected benefit of securely engaging the biochip within the apparatus as taught by Wilding et al (Column 13, lines 26-35).

Regarding Claim 57, Hollis et al disclose the apparatus wherein the fluidic system is in direct contact with the biochip (Column 6, lines 40-41 and Fig. 1-4).

Regarding Claim 58, Hollis et al disclose the apparatus includes a flow cell (Column 6, lines 29-67 and Fig. 1-4).

Regarding Claim 59, Hollis et al disclose the apparatus wherein the flow cell substantially surrounds the active area of the biochip (Column 6, lines 29-67 and Fig. 1-4).

Regarding Claim 60, Wilding et al teach their similar apparatus wherein the optical window is a ports window i.e. the ports (# 14 & #16) traverse the window (#29) (see Fig. 1).

Regarding Claim 61, Hollis et al disclose the apparatus wherein the flow cell has a defined volume i.e. flow cells of defined size also have defined volume (Column 15, lines 12-37).

Regarding Claim 62, Hollis et al disclose the apparatus wherein the flow cell has a defined volume i.e. flow cells of defined size also have defined volume (Column 15, lines 12-37)

but they are silent regarding the volume of the flow cell. However, Wilding et al teach the similar apparatus wherein the flow cell has a defined volume from substantially 5 to 10 μ l (Column 16, lines 9-12) wherein samples having a very small are efficiently analyzed (Column 3, lines 12-65). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the μ l volumes taught by Wilding et al to the apparatus of Hollis et al for the expected benefit of efficiently and rapidly analyzing sample of very small size as taught by Wilding et al (Column 3, lines 12-65).

Regarding Claims 63 and 64, Hollis et al disclose the apparatus comprising an outlet port whereby fluid is transferred out of the apparatus (see right side of Fig. 19) but they are silent regarding a reservoir attached to the outlet. However, Wilding et al teach the similar apparatus wherein a reservoir (i.e. a receptacle of adequate capacity) is attached to the outlet whereby sample and reaction products are safely contained for disposal (Column 19, lines 48-54). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the reservoir (e.g. tube) of Wilding et al to the outlet port of Hollis et al for the expected benefit of safely containing fluids to be disposed as taught by Wilding et al (Column 19, lines 48-54).

Regarding Claim 65, Wilding et al teach their waste reservoir is appropriately sized to contain fluids (Column 19, lines 48-54) which clearly suggests that the reservoir is expandable/changeable to accommodate various samples. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the reservoirs of Hollis et al and Wilding et al as suggested by the Wilding et al and to provide an expandable waste reservoir to thereby accommodate various size samples and reagent volumes (Column 19, lines 48-54).

Regarding Claim 66, Hollis et al. do not teach the circuit board is a PCMCIA board. However, The courts have stated that the greater the physical similarities between the claimed species and any species disclosed in the prior art, the greater the expectation that the claimed

subject matter will function in an equivalent manner (see *Dillon*, 99 F.2d at 696, 16 USPQ2d at 1904). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify circuit board of Hollis et al. with the claimed PCMCIA board based on the functional and physical similarities between the PCMCIA board and circuit board of Hollis et al.

Regarding Claim 67, Hollis et al. disclose the circuit board further including wires connecting the biochip to the circuit board (Column 4, lines 23-31 and Fig. 1).

Regarding Claim 68, Hollis et al. disclose the circuit board wherein the wires are embedded in a protective material i.e. semiconductor or dielectric material (Column 14, lines 42-48).

Regarding Claim 69, Hollis et al disclose the apparatus comprising a fluidic system comprising an inlet port and an outlet port (Column 14, lines 26-65 and Fig. 18-20) but they do not teach the apparatus further comprises a window. However, Wilding et al teach their similar apparatus comprising a fluidic system wherein the fluidic system further comprises an optical window having a planar bottom surface parallel to the upper surface of the biochip wherein the inlet and outlet ports are above the upper surface of the biochip (Fig. 1). Wilding et al further teach that the arrangement of their apparatus facilitates dynamic viewing of the contents of the apparatus (Column 10, lines 17-28). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the apparatus of Hollis et al by incorporating the optical window and surface inlet and outlet ports as taught by Wilding et al for the expected benefits of facilitating dynamic viewing the contents of the apparatus as taught by Wilding et al (Column 10, lines 17-28).

Conclusion

9. No claim is allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
August 12, 2003